

In re National Prescription Opiate Litigation: MDL 2804
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum in Opposition to Manufacturer Defendants' Motion for Summary Judgment on Plaintiffs' Public Nuisance Claims (Dkt. # 1942)

Opposing Parties: Plaintiffs Summit County and Cuyahoga Counties

Issue 1: Have Plaintiffs appropriately defined a public nuisance?

Answer: Yes. The Court has already determined that Plaintiffs' public nuisance claims "fit" within Ohio law. *See* Dkt. # 1203 at 39. Thus, as a matter of law, Plaintiffs have appropriately defined an actionable public nuisance.

Issue 2: Did the Manufacturer Defendants sustain their burden of showing entitlement to summary judgment dismissal of Plaintiffs' absolute public nuisance claims?

Answer: No. The Manufacturer Defendants have failed to show the absence of trial issues of fact as to the requisite elements of an absolute public nuisance claim, to wit: (1) the existence of a public nuisance; (2) intentional or unlawful conduct by the Manufacturer Defendants; and (3) proximate cause. As to the existence of a public nuisance, a "public nuisance is defined as an unreasonable interference with a right common to the general public." Restatement (Second) of Torts, § 821B(1) (1979). Ohio law recognizes that public nuisances include "a significant interference with the public health" *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002). As shown in Plaintiffs' Motion for Partial Summary Adjudication of Their Equitable Claims for Abatement of an Absolute Public Nuisance (Dkt. # 1880) incorporated herein, the epidemic of opioid availability and use has interfered with a "public right," e.g. public health, and constitutes a public nuisance. As to intentional and unlawful conduct, the record is replete with evidence of the Manufacturer Defendants' intentional conduct, including deliberate, false and misleading marketing strategies that served to distort the needs, wants and demand for opioids, and unlawful conduct in the violation of the Controlled Substances Act ("CSA"). As to causation, the legal challenges concerning proximate cause have already been addressed by this Court. *See* Dkt. # 1203 at 7-10. As to factual challenges, Plaintiffs incorporate their Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation, which shows each Manufacturer Defendant, through a deceptive and illegal marketing campaign and a failure to prevent diversion of its prescription opioids, caused the opioid crisis in Summit and Cuyahoga Counties.

Issue 3: Can Plaintiffs prove a predicate violation to support their statutory nuisance claim?

Answer: Yes. Plaintiffs can show a predicate violation to support their statutory public nuisance claim, including, but not limited to, violation of the CSA by each of the Manufacturer Defendants. *See* Plaintiffs' Motion for Summary Judgment on Violations Under CSA at pp. 25-68 (Dkt. # 1924).

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE
LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO MANUFACTURER DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' PUBLIC NUISANCE CLAIMS
(DKT. # 1942)**

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INTRODUCTION

The Manufacturer Defendants’ Motion for Summary Judgment on Plaintiffs’ Public Nuisance Claims (Dkt. # 1942) should be denied. First, much of the motion is simply a repackaging of legal arguments raised by the Manufacturer Defendants in their Rule 12(b)(6) motion to dismiss – a motion that this Court has already denied. The attempt to revive previously rejected legal pleading challenges under the guise of a motion for summary judgment is procedurally improper. Second, the Manufacturer Defendants have not carried their burden of showing that there is no genuine dispute as to any material fact. Merely parroting the phrase “an absence of evidence” or the like is not sufficient to demonstrate an entitlement to summary judgment as a matter of law – particularly where, as here, the assertions are conclusively contradicted by the record. Indeed, the Manufacturer Defendants’ own submissions highlight the existence of the public nuisance¹ and triable issues of fact as to the Manufacturer Defendants’ role in creating and fueling same. And, in any event, Plaintiffs have raised triable issues of fact sufficient to warrant denial of the motion. There can be little doubt that the opioid crisis – an epidemic of opioid availability and use – significantly interferes with the public health and constitutes a public nuisance in both Cuyahoga and Summit Counties, and that the Manufacturer Defendants created and sustained that public nuisance through both intentional and unlawful conduct. The motion for summary judgment on Plaintiffs’ nuisance claims should be denied in its entirety.

ARGUMENT

I. PLAINTIFFS HAVE APPROPRIATELY DEFINED A PUBLIC NUISANCE

As an initial ground for summary judgment, the Manufacturer Defendants feign an inability to discern the public nuisance at issue in this case, asserting that the public nuisance claims are “undefined” and “amorphous.” Def. Mem. at 1-4. This argument is an improper effort to relitigate

¹ In fact, Plaintiffs Summit and Cuyahoga Counties’ Motion for Partial Summary Adjudication of Their Equitable Claims for Abatement of an Absolute Public Nuisance (Dkt. # 1880) sets forth undisputed facts demonstrating that the epidemic of opioid availability and use has interfered with a public right and thus is an actionable public nuisance. At a minimum, the wealth of evidence provided by plaintiffs in that motion precludes such judgment for the Manufacturer Defendants on this point.

the Manufacturer Defendants’ motion to dismiss. Indeed, this argument is impossible to reconcile with the fact that Plaintiffs’ absolute public nuisance claims have withstood a Rule 12(b)(6) challenge by the Manufacturer Defendants, wherein the Court was required to determine whether the complaint “contain[ed] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has facial plausibility, the Supreme Court has explained, “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* This Court has already determined that Plaintiffs’ absolute public nuisance claims “fit” within Ohio law. *See* Dkt. # 1203 at 39. Thus, as a matter of law, Plaintiffs have appropriately defined an actionable public nuisance, and this ground for summary judgment must be rejected. *See Faiveley Transp. USA, Inc. v. Wabtec Corp.*, No. 10 Civ. 4062, 2011 U.S. Dist. LEXIS 52945, at *12, 2011 WL 1899730, at *4 (S.D.N.Y. May 13, 2011) (rejecting summary judgment motion as “thinly disguised attempt to relitigate issues” already lost on motion to dismiss).

II. THE MANUFACTURER DEFENDANTS HAVE NOT SUSTAINED THEIR BURDEN OF SHOWING AN ENTITLEMENT TO JUDGMENT AS A MATTER OF LAW ON PLAINTIFFS’ ABSOLUTE NUISANCE CLAIMS

To sustain their claims for an absolute public nuisance, Plaintiffs must establish that a public nuisance exists, and the Manufacturer Defendants’ intentional or unlawful conduct renders them liable for the nuisance. *See City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002); *Taylor v. Cincinnati*, 55 N.E.2d 724, 730 (Ohio 1944) (absolute nuisance arises or results from “the unlawful doing of anything . . . which results in injury to another”); *Angerman v. Burick*, 2003-Ohio-1469, ¶ 9 (Ct. App.) (absolute nuisance consists of, *inter alia*, “an act involving culpable and unlawful conduct causing unintentional harm”) (Batchelder, J.); *Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859, 863 (N.D. Ohio 2017) (“intentional conduct, standing alone, supports an absolute-nuisance claim”). As set forth below, the record is replete with evidence demonstrating, at minimum, triable issues of fact, if not conclusive and undisputed proof of the elements of Plaintiffs’ absolute nuisance claims being challenged by the Manufacturer Defendants in their motion.

A. The Evidence Demonstrates the Existence of a Significant Interference with a “Public Right” by the Manufacturer Defendants

A “public nuisance is defined as an unreasonable interference with a right common to the general public.” Restatement (Second) of Torts, § 821B(1) (1979) (hereafter “Restatement”). Ohio has adopted the Restatement’s definition of public nuisance. *Beretta*, 768 N.E.2d at 1142. The definition of public nuisance “is couched in broad language,” *id.*, and both the Ohio Supreme Court and the Restatement recognize that public nuisances include “a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.” *Beretta*, 768 N.E.2d at 1142; Restatement § 821B(2)(a). Thus, in *Beretta*, the Ohio Supreme Court held that the city’s allegation that handgun manufacturers “created and maintained a public nuisance by manufacturing, marketing, distributing, and selling firearms in ways that unreasonably interfere with the public health, welfare, and safety in Cincinnati and that the residents of Cincinnati have a common right to be free from such conduct” stated a public nuisance claim. *Beretta*, 768 N.E.2d at 1142; *see also City of Cincinnati v. Deutsche Bank Nat’l Trust Co.*, 863 F.3d 474, 477 (6th Cir. 2017) (under Ohio law, public nuisance includes interferences with “a right to public health”). Likewise, here, Plaintiffs’ public nuisance claims fall within the legal framework: the Manufacturer Defendants created and maintained a public nuisance by manufacturing, distributing and selling opioids in ways that unreasonably interfered with, *inter alia*, the public health.

Notwithstanding this well-established precedent, the Manufacturer Defendants insist that, *as a matter of law*, the opioid epidemic cannot constitute a public nuisance because it does not interfere with a “public right.” *See* Def. Mem. at 4-7.² This argument, however, was by definition rejected when the Court denied the Manufacturer Defendants’ motion to dismiss Plaintiffs’ absolute public nuisance claims. *See* Dkt. # 1203. Moreover, this Court has rejected Defendants’ contention that the “public health” and “public right” are “not synonymous,” because it “conveniently overlook[s] large portions of the Restatement,” demonstrating that “‘public health’ has traditionally been considered a ‘public

² The Manufacturer Defendants assert that the “public right” issue was not addressed at the pleading stage. Def. Mem. at 7. This is incorrect. The Manufacturer Defendants raised this argument at page 43 of their motion to dismiss (Dkt. # 499), and Plaintiffs responded at pages 6-11 of their omnibus opposition. Dkt. # 654.

right.” Dkt. # 1680 at 18-19. Indeed, this Court noted in its Opinion and Order on the motions to dismiss:

It is accurate to describe the opioid epidemic as a man-made plague, twenty years in the making. The pain, death, and heartache it has wrought cannot be overstated. As this Court has previously stated, it is hard to find anyone in Ohio who does not have a family member, a friend, a parent of a friend, or a child of a friend who has not been affected.

Dkt. # 1203 at 38. Given this ruling, it is undeniable that the opioid epidemic “significantly interfere[s] with the public health” – which is a “public right” – and constitutes a public nuisance. *Beretta*, 768 N.E.2d at 1142.³

The Manufacturer Defendants’ renewed efforts to recast Plaintiffs’ claims as an amalgamation of private, personal injury claims suffered by Summit County and Cuyahoga County residents also fails. This case does not hinge on whether individual Summit County and Cuyahoga County residents have a right to be personally and individually “safe” from defective products. *See* Def. Mem. at 6. Rather, Plaintiffs’ claim is that Defendants, including the Manufacturer Defendants, have engaged in conduct that creates “widespread harm and widespread costs to the [counties] as a whole and to [their] citizens individually.” *Beretta*, 768 N.E.2d at 1142. Moreover, even if the only measure of this nuisance were the number of people affected, contrary to the Manufacturer Defendants’ suggestion, *see* Def. Mem. at 5, that alone can establish that a public nuisance exists. As explained in the comments to Restatement § 821B, a public nuisance can be something that “affect[s] the health of so many persons so as to involve the interests of the public at large.” *Id.*, Cmt. g. “It is not . . . necessary that the entire community be affected by a public nuisance, so long as the nuisance will interfere with those who come in contact with it in the exercise of a public rights or it otherwise affects the interests of the

³ Ohio law is in the mainstream in recognizing that an interference with the public health constitutes an interference with a “public right.” In fact, multiple courts in opioids litigation have explicitly rejected Defendants’ “public right” argument. *See, e.g., In re Opioid Litigation*, No. 40000/2017 (N.Y. Sup. Ct. June 18, 2018), at 28; *State of West Virginia, ex rel. Morrissey v. AmerisourceBergen Drug Corp.*, No. 12-C-141 (W. Va. Cir. Ct. Dec. 12, 2014), at 19; *Kentucky v. Endo Health Solutions Inc.*, No. 17-CI-1147 (Franklin Cir. Ct. July 10, 2018), at 13-14; *Alaska v. Purdue Pharma L.P.*, Case No. 3AN-17-09966CI (Anchorage Sup. Ct. July 12, 2018), at 8-9. Yet more have implicitly rejected the argument. *See, e.g., California v. Purdue Pharma L.P.*, No. 30-2014-00725287 (Cal. Super. Ct. Feb. 13, 2018); *South Carolina v. Purdue Pharma L.P.*, No. 2017-CP-40-04872 (S.C. Ct. Com. Pl. Apr. 12, 2018); *Washington v. Purdue Pharma L.P.*, No. 17-2-25505-0 SEA at 3 (Wash. Super. Ct. May 14, 2018); *State of New Hampshire v. Purdue Pharma, L.P.*, Case No. 217-2017-CV-00402 at 27-28 (N.H. Super. Ct. Sept. 18, 2018).

community at large. *Id.* The opioid crisis in Summit and Cuyahoga Counties fits squarely within this definition.

The undisputed facts set forth in Plaintiffs Summit and Cuyahoga Counties' Motion for Partial Summary Adjudication of Their Equitable Claims for Abatement of an Absolute Public Nuisance (Dkt. # 1880), incorporated by reference here, confirm that the epidemic of opioid availability and use has interfered with a "public right." In that motion, Plaintiffs provide evidence that painstakingly details how the opioid epidemic has devastated both Summit and Cuyahoga Counties: increases in prescription opioid overdose death rates, increases in neonatal abstinence syndrome, and impacts on treatment providers, law enforcement, first responders, hospitals, children services, the criminal justice system, the medical examiners, and families. *Id.* at 5-14. To argue that these circumstances do not significantly impact a public right is not just incorrect, but also callous and disingenuous. In fact, the evidence shows that the Manufacturer Defendants themselves *admit* that the opioid crisis is a public health crisis. *See id.* at 19-20 (Manufacturer Defendant Mallinckrodt); at 20-21 (Manufacturer Defendant Purdue); at 21 (Manufacturer Defendant Teva); at 21-22 (Manufacturer Defendant Endo).

B. The Evidence Demonstrates that the Manufacturer Defendants Proximally Caused a Public Nuisance

In response to the proximate cause arguments raised in section II(B) of the Manufacturer Defendants' Memorandum, Plaintiffs incorporate by reference their Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation. In that Opposition, Plaintiffs show that each Manufacturer Defendant, through a deceptive and illegal marketing campaign and a failure to prevent diversion of its prescription opioids, caused the opioid crisis in Summit and Cuyahoga Counties. Plaintiffs demonstrate this causal connection with both statistical analysis of aggregate evidence by prominent public health economists and more individualized proof that each Manufacturer Defendants' intentional and negligent conduct was expected to and did cause the epidemic of opioid availability and use.

In addition, two points warrant brief mention here. First, the Manufacturer Defendants erroneously suggest that the proximate cause standard differs at the motion to dismiss stage from that at the summary judgment stage. *See* Def. Mem. at 8. Their supposition is incorrect. *See, e.g., Mendoza v. Perez*, 754 F.3d 1002, 1016 n9 (D.C. Cir. 2014) (“[D]efendants challenge the sufficiency of those facts to meet the legal standard for injury in fact, causation, and redressability. The standard for resolution of these legal arguments is the same at the motion to dismiss stage as it is on a motion for summary judgment.”).

Second, the Manufacturer Defendants suggest that in order to establish proximate cause, Plaintiffs must as a matter of law establish that the Manufacturer Defendants had “sufficient control over *the product* that caused the injury.” Def. Mem. at 78 (emphasis added). This, too, is incorrect. Instructive here is *Beretta*, where the Ohio Supreme Court rejected a similar argument raised by gun manufacturers, reasoning:

. . . Contrary to [the gun manufacturers’] position, it is not fatal to [the City’s] public nuisance claim that [gun manufacturers] did not control the actual firearms at the moment the harm occurred.

[The City’s] complaint alleged that [gun manufacturers] created a nuisance through their ongoing conduct in marketing, distributing, and selling firearms in a manner that facilitated their flow into the illegal market. Thus, [the City] alleged that [gun manufacturers] control the creation and supply of this illegal, secondary market for firearms, not the actual use of the firearms that cause injury. Just as the individuals who fire the guns are held accountable for the injuries sustained, [gun manufacturers] can be held liable for creating the alleged nuisance.

Beretta, 768 N.E.2d at 1443; *see also* Dkt. # 1680 at 19 (Court recognizing that the opioid “defendants’ conduct in carrying out their business activities is the instrumentality by which the nuisance was created and fueled”). That is precisely what the evidence shows here: that the Manufacturer Defendants controlled the marketing, distribution, and sale of opioids that created, extended, and sustained the opioid crisis in Summit and Cuyahoga Counties. *See* Plaintiffs’ Consolidated Memorandum in Opposition to Defendants’ Motions for Summary Judgment on Proof of Causation.

Simply put, the record contains ample evidence showing that the Manufacturer Defendants controlled the instrumentalities – the deceptive marketing to expand and maintain the market for opioids and the failure to control distribution to prevent diversion into Summit and Cuyahoga Counties – that created and continued the devastating opioid epidemic and caused it to spread through Summit and Cuyahoga Counties.

In short, *legal* issues concerning proximate cause were addressed by this Court at the motion to dismiss stage, *see* Opinion and Order, Dkt. # 1203 at 7-10 (addressing proximate cause and remoteness and denying Defendants’ Rule 12(b)(6) motions), and are not appropriate for relitigation here. *See Faiveley Transp.*, 2011 U.S. Dist. LEXIS 52945, at *12, 2011 WL 1899730, at *4 (rejecting summary judgment motion as “thinly disguised attempt to relitigate issues” already lost on motion to dismiss). The robust *evidence* demonstrating that, at a minimum, genuine issues of material fact with respect to the Manufacturer Defendants’ causation of the public nuisance is set out, as noted above, in Plaintiffs’ Consolidated Memorandum in Opposition to Defendants’ Motions for Summary Judgment on Proof of Causation.

C. The Evidence Demonstrates that the Manufacturer Defendants Engaged in Intentional and Unlawful Conduct

Contrary to the Manufacturer Defendants’ contention, Plaintiffs are not limited to an “intent-based absolute public nuisance claim.” Def. Mem. at 11. Rather, the law is clear that an absolute nuisance claim may be predicated on, *inter alia*, intentional conduct *or* unlawful conduct. *See Taylor*, 55 N.E.2d at 727-729; *Beretta*, 768 N.E.2d at 1143 n4 (“[w]ith an absolute nuisance, the wrongful act is either intentional or unlawful and strict liability attaches notwithstanding the absence of fault . . .”); *Angerman*, 2003-Ohio-1469, ¶ 9 (absolute nuisance consists of, *inter alia*, “an act involving culpable and unlawful conduct causing unintentional harm”); *Nottke*, 264 F. Supp. 3d at 863 (“intentional conduct, standing alone, supports an absolute nuisance claim”). Plaintiffs’ absolute nuisance claim clearly implicates both intentional and unlawful culpable conduct and, as discussed below, the record is replete with evidence supporting the existence of both.

The record demonstrates that the Manufacturer Defendants engaged in culpable intentional acts. “Intentional, in this context, means not that a wrong or the existence of a nuisance was intended but that the creator of it intended to *bring about the conditions* which are in fact found to be a nuisance.” *Nottke*, 264 F. Supp. 3d at 863 (internal quotations, brackets and citation omitted). Stated differently, “[w]here the harm and resulting damage are *the necessary consequences of* just what the defendant is doing . . .” the intentional conduct element is satisfied. *Id.* at 864 (emphasis added); *see Taylor*, 55 N.E.2d at 727. Here, Plaintiffs have alleged, and the record demonstrates, that the opioid epidemic was the necessary consequence of the Manufacturer Defendants’ intentional conduct. The Manufacturer Defendants’ protestations to the contrary, premised merely on a conclusory assertion that the “record is devoid of evidence” of intent, is insufficient to sustain their burden for summary judgment. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 332 (1986) (“Plainly, a conclusory assertion that the nonmoving party has no evidence is insufficient”) (Justice Brennan dissenting) (cited with approval in *Angelo v. Kroger Co.*, 1987 U.S. App. LEXIS 11965, *25, 828 F.2d 19 (6th Cir. 1987); *E-Poch Props. v. TRW Auto. U.S.*, No. 1:05-cv-01669, 2007 U.S. Dist. LEXIS 14820, at *4 (N.D. Ohio Mar. 2, 2007) (“it is not enough to move for summary judgment . . . with a conclusory assertion that the [non-moving party] has no evidence to prove his case”) (quoting *Celotex*, 477 U.S. at 328). This is particularly so where, as here, the claim is completely belied by the evidence in the record.

Fact and expert evidence developed in discovery point strongly to the Manufacturer Defendants’ deliberate, sophisticated, and successful effort to change the standard of care in prescribing and using opioids by, *inter alia*, intentionally misrepresenting their risks, particularly the risk of addiction. For example, Dr. Russell Portenoy, a prominent key opinion leader funded and relied upon by Manufacturer Defendants, affirmed both the culpability and the efficacy of Manufacturer Defendants’ marketing misconduct:

Q. To the extent we have a public health problem in this country, do you think it’s right for Purdue to say they bore no responsibility for that problem?

A. Right. No, I’m on – I have come to believe that is not right.

Q. What is right?

A. The pharmaceutical industry should accept partial responsibility for the public health problem that has emerged . . . all the positive messages and packaged into marketing without concurrently providing the medical community and the public with the context and the kinds of education related to risk . . . that messaging was not included in many – in much of the marketing work that was done by the companies during this period of time. And I have come to believe that that’s in part what drove the kind of prescribing

Russell K. Portenoy, M.D., Dep. (1/24/19), Dkt. # 1969-11 at 267:5-271:5.

Q. You believe the drug companies used the positive statements that you made about opioids to portray opioid treatment as safe and effective correct?

A. Yes.

Q. You believe the drug companies used your statements without also using your accompanying discussion of the risk that you included in papers and other things that you wrote, correct?

A. Yes.

Id. at 66:3-16. Dr. Portenoy affirmed that the Manufacturer Defendants deliberately engaged in marketing opioids “without concurrently providing the medical community and the public with the context and the kinds of education related to the risk.” *Id.* at 267:5-271:5. These intentional promotional activities “contributed to the rising incidence of drug addiction and overdoses.” Ex. A, Declaration of Russell K. Portenoy, M.D., (12/13/18) at 3, 35.⁴

Additional evidence of the Manufacturer Defendants’ intent and impact include, in addition to those referenced in oppositions to various defendants’ individual motions for summary judgment:

- Purdue’s effort to persuade prescribers and patients that OxyContin was weaker than morphine, even though it was two (2) times more potent. *See* Ex. B, Richard Sackler Dep. (3/8/19) at 394:3-396:20, 399:14-406:17, 411:13-413:13.

⁴ Dr. Portenoy stated specifically that “drug companies used [his] work to provide content and expert support for a strongly positive message about opioids, and in much of the material produced by drug companies, the content lacked context and warnings, and in so doing, presented a message that lacked balance. The effect was to promote opioid therapy to prescribers.” Further, “communications from drug manufacturers and their vendors encouraged opioid prescribing. One result was prescribing to patients who were inappropriate for chronic opioid therapy. Another was prescribing by physicians who lacked the skills in assessment and management of adverse outcomes when they occurred.” Portenoy Dec. at 41, 49. Dr. Portenoy noted, too, that in even a rare risk of de novo iatrogenic addiction becomes significant when the prevalence of use increases. Portenoy Dec. at 32.

- Multiple defendants influenced the 2009 Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain issued by the American Pain Society and American Academy of Pain Medicine. *See* Joel Saper, M.D. Dep. (1/11/19), Dkt. # 1970-15 at 45:7-22 (“[O]pioids are different . . . advocacy for those drugs has to be based on medical common sense independent of the financial flow of dollars, and it was my growing fear that that was not the case in the case of these guidelines and programming within the various organizations.”).

- Mallinckrodt’s eager, unlawful shipment of its opioids, which it promoted through its unbranded C.A.R.E.S Alliance as “rare” (Ex. C, Kevin Webb FRCP 30(b)(6) Dep. (1/17/19), at 99:12-104:9 and Ex. 16 (“*Defeat Chronic Pain Now!*”), at 7, even while internally joking that they were addictive, “Just like Doritos. Keep eating. We’ll make more.” Ex. D, MNK-T1_0000559532.

- As described in Plaintiffs’ Opposition to Janssen’s Motion for Summary Judgment, Janssen’s targeting of elementary school children by marketing its opioids to their coaches. *See* Ex. E, JAN-MS-00393295 at 2; Gary Vorsanger Dep. (12/5/18), Dkt. # 1971-18 at 675:6-18.

- Allergan’s intentional marketing campaign to increase availability and sales of generic opioids by, among other things, disseminating sales training materials that advised sales representatives that “fear of addiction” and “opioid phobia” were “barrier[s] to treatment of pain” (Jennifer Altier Dep. (8/2/18), Dkt. # 1956-6 at 108:21-111:5), while simultaneously marketing and profiting from the sale of opioid addiction treatments. *See* David Myers Dep. (12/13/18), Dkt. # 1968-14 at 152:9-153:24.

- TEVA’s willful failure to implement an effective suspicious order monitoring system, which, as acknowledged by its own DEA Compliance Manager, was a contributing factor to the opioid epidemic. *See* Ex. F, TEVA_MDL_A_01060005, at -007; Colleen McGinn Dep. (12/14/18), Dkt. # 1966-20 at 98:3-101:10, and 134:6 to 135:22.

Indeed, the very same evidence that the Manufacturer Defendants submitted in support of their motion raises triable issues of fact as culpability. The excerpted portions of Professor David Cutler’s report includes the conclusion that “the increased demand for illicit opioids would not have occurred absent defendants’ misconduct resulting in increased shipments of prescription opioids and

CSA registrants' failure to identify excessive shipments, the resulting harm relating to illicit opioids is appropriately attributable to defendants' actions." Dkt. # 1942, Ex. 1 to Knapp Dec. at ¶ 63. Similarly, excerpted portions of Professor Meredith Rosenthal's report contains the conclusion that "... the perceptions of physicians and the public evolved as a direct result of the alleged [marketing] misconduct.[] These changes – which were the result of the Defendants' actions – would have affected the receptiveness of prescribers and patients to promotional messages about the safety and effectiveness of opioids." Dkt. # 1942, Ex. 2 to Knapp Dec. at ¶ 57. Professor Rosenthal further concludes, "... there is a causal relationship between the Defendants' promotion and prescriptions of opioids so that if the allegations of misconduct are proven true, impact can be found" *Id.* at ¶ 64.

Notably, the reports of both Professors Cutler and Rosenthal make reference to certain conclusions made by expert Professor Matthew Perri, who stated, among other things, that based upon his review of Defendants' marketing activities, the Defendants "worked to create aggressive[] marketing strategies for opioids which served to distort needs, wants, and demand for opioids. Evidence that Defendants' marketing was aggressive is seen in marketing and brand plans,[] tactical plans, sales training[], and other documents and communications cited throughout this Report." Report of Matthew Perri III, BS Pharm, PhD, RPh, Dkt. # 2000-19 at 73-75. The marketing tactics were intentionally employed to gain market share and expand the overall market for opioids, which in turn "*led* to the dramatic rise in utilization of opioids in the U.S." *Id.* at 155 (emphasis added); *see also* Report of Anna Lembke, MD, Dkt. # 2000-10 at 75 ("the Pharmaceutical Opioid Industry made misleading marketing claims to promote []misconceptions [T]hese misconceptions were the single most significant factor giving rise to the massive increase in sale of opioids and the resulting epidemic of dependence and addiction . . ."); *Id.* at 63-75 (listing misrepresentations). Accordingly, and contrary to the Manufacturer Defendants' contention, the record demonstrates, at minimum, triable issues of fact as to the intentional conduct by the Manufacturer Defendants, the necessary consequence of which was the opioid epidemic.

With respect to unlawful conduct, the record contains undisputed evidence of the Manufacturer Defendants' violation of, *inter alia*, the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq.* Plaintiffs incorporate by reference their Motion and Memorandum of Law for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (hereafter "Plaintiffs' Motion for Summary Judgment on Violations Under CSA") (Dkt. # 1924). This motion details the obligations imposed upon, *inter alia*, the Manufacturer Defendants under the CSA, and further summarizes the evidence proving the Manufacturer Defendants' violations of their obligations under the CSA. *See id.* at 3-14 (the obligations imposed under the CSA and Defendants acknowledgment of same); 26-27 (summarizing evidence of Mallinckrodt's violations of the CSA); 37-40 (summarizing evidence of Purdue's violations of the CSA); 40-43 (summarizing evidence of Teva's violations of the CSA); 43-54 (summarizing evidence of Endo's violations of the CSA); 54-62 (summarizing evidence of J&J's violations of the CSA); 62-68 (summarizing evidence of Allergan's violations of the CSA).

III. PLAINTIFFS CAN PROVE PREDICATE VIOLATIONS SUFFICIENT TO SUPPORT THEIR STATUTORY NUISANCE CLAIM

Plaintiffs have asserted claims for statutory public nuisance.⁵ Ohio Revised Code § 4729.35 provides that:

The violation by a . . . person of any laws of Ohio or the United States of America . . . controlling the distribution of a drug of abuse as defined in section 3719.011 of the Revised Code, is hereby declared to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance.

Opioids are a "drug of abuse." *See* Ohio Revised Code § 3719.011(A); Ohio Revised Code § 3719.01(C) & (D). In their motion for summary judgment, the Manufacturer Defendants make the conclusory and legally unsupported contention that "Plaintiffs have never explained what conduct of

⁵ Under Ohio common law, a public nuisance is "an unreasonable interference with a right common to the general public" and an "unreasonable interference includes . . . conduct that is contrary to a statute, ordinance, or regulation." *Beretta*, 768 N.E.2d at 1142 (quoting Restatement, § 821B). Claims of "statutory or regulatory violations involving public health or safety," are common examples of conduct constituting a common law public nuisance, and the CSA violations are violations of law which constitute an unreasonable interference with public rights under the Section 821B test in *Beretta*.

Manufacturer Defendants constitutes the predicate act for purposes of their statutory nuisance claim.” Def. Mem. at 12. Predicate violations are identified in the complaint, and were addressed in Defendants’ motions to dismiss and Plaintiffs’ omnibus opposition. The Report and Recommendation addressing the motions to dismiss specifically and extensively analyzed the question of whether Plaintiffs had made sufficient factual allegations of predicate violations underlying its statutory public nuisance claims and concluded that they had. *See* Dkt. # 1025 at 70-72 (identifying alleged violations of law and rules alleged to “require[e] [the Manufacturer Defendants] to maintain diversion controls and to create a system to disclose suspicious orders, report such orders, and adhere to sales quotas set by the DEA” and noting that “the complaint identifies specific statutes as bases for alleged liability and also states that the claimed violations include, but are not limited to, conduct proscribed by Ohio and federal law”). The Manufacturer Defendants’ contention is thus an improper effort to relitigate the Rule 12(b)(6) motion and should be rejected. *See Faiveley Transp.*, 2011 U.S. Dist. LEXIS 52945, at *12, 2011 WL 1899730, at *4.

Similarly, as noted above, a conclusory assertion that there is an absence of “evidence of *an* actual predicate violation,” *see* Def. Mem. at 12 (emphasis added), is insufficient to sustain the Manufacturer Defendants’ burden for summary judgment. *See Celotex Corp.*, 477 U.S. at 332; *E-Poch Props.* 2007 U.S. Dist. LEXIS 14820, at *4. Indeed, the *only* predicate violation the Manufacturing Defendants even discuss in their motion is their alleged violations of the CSA. *See* Def. Mem. at 12. There, of course, can be no disputing that the CSA (together with its implementing regulations) is a “law[] of . . . the United States of America . . . controlling the distribution of a drug of abuse.” *See* Ohio Revised Code § 4729.35. As set forth in Plaintiffs’ Motion for Summary Judgment on Violations, there is undisputed evidence of the Manufacturer Defendants’ repeated violations of the CSA, including undisputed evidence that the Manufacturer Defendants failed to maintain effective controls, and failed to investigate, report and take appropriate steps to halt orders that they knew or should

have known were suspicious. The evidence is not, as characterized by the Manufacturer Defendants, merely “vague references” and “general assertions that Manufacturer Defendants turned a blind eye to suspicious order monitoring requirements” Def. Mem. at 12. To the contrary, the evidence contains numerous expert reports, as well as the Manufacturer Defendants’ own documentation, that establish repeated and ongoing violations of federal law. *See* Plaintiffs’ Motion for Summary Judgment on Violations Under CSA, Dkt. # 1924 at 25-68. Simply put, contrary to the Manufacturer Defendants’ contention, Plaintiffs have indeed made “a showing” of “an actual predicate violation” by the Manufacturer Defendants. This showing is sufficient to defeat the Manufacturer Defendants’ motion for summary judgment.⁶

CONCLUSION

The Manufacturer Defendants’ Motion for Summary Judgment on Plaintiffs’ Public Nuisance Claims (Dkt. # 1942) should be denied in its entirety.

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Respectfully submitted,

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⁶ Plaintiffs should not be left to guess what evidence the Manufacturer Defendants contend is lacking as to the other predicate violations. The Sixth Circuit, quoting Justice Brennan’s dissent in *Celotex* with approval, wrote: “Plainly, a conclusory assertion that the nonmoving party has no evidence is insufficient. Such a ‘burden’ of production is no burden at all and would simply permit summary judgment procedure to be converted into a tool for harassment. . . .” *Angelo*, 1987 U.S. App. LEXIS 11965, *25, 828 F.2d 19.

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